UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/040,103	03/17/98	MASON J	52494-21

HM12/0909

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EXAMINER	
GOZO,D	
ART UNIT	**PAPER NUMBER**
1636	11

DATE MAILED: 09/09/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)

1- File Copy

Office Action Summary	Application No. 09/040,103	Applicant(s) Mason
	Examiner David Guzo	Group Art Unit 1636

☒ Responsive to communication(s) filed on *Jul 26, 1999*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-41* is/are pending in the application.

Of the above, claim(s) *22-35, 39, and 40* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-21, 36-38, and 41* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *7*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ attachment on Deposits of Biological Materials

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Applicant's election with traverse of Group I, Claims 1-21, 36-38 and 41, in Paper No. 10 is acknowledged. The traversal is on the ground(s) that claims 39-40 are directed to pharmaceutical compositions comprising the retroviral particles of claims 20 and 2, respectively, and hence are sufficiently related so as to be included in Group I. Applicants indicate that the methods of claims 22-35 are directed to uses of the retroviral particles of group I, they should be presented as a single invention and a search of both groups would not be a serious burden on the examiner.

This is not found persuasive because the examiner notes that the subject matter of claims 39 and 40 is distinct from the retroviral vector compositions clams of Group I in that claims 39 and 40 are directed to **pharmaceutical compositions** for treatment of disease conditions. A search of this invention recited in claims 39 and 40 would not be co-extensive with a search of the subject matter of Group I and would involve a search of the gene therapy art, the body treatment art, etc. The same is true of the *in vivo/ex vivo* gene therapy methods recited in claims 22-35. It is noted again that the retroviral vectors of Group I can be used in a materially, patentably distinct, method of using, i.e. for use as an expression vector for expressing genes of interest in cells *in vitro*.

This requirement is still deemed proper and is therefore made FINAL.

1. Claims 22-35 and 39-40 are withdrawn from further consideration by the examiner, 37

CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 10.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 1, 3-6, 8-11, 13-21 and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Rother et al.

Applicants and Rother et al. (U.S. Patent 5,871,997, issued 2/16/99, filed 3/6/95, see whole document, particularly Column 15 and Examples 1-7) recite methods for preparing stable packaging and producer retroviral cell lines for generation of human serum-resistant retroviral vector particles which comprise introducing one or more packaging vectors into a non-primate mammalian cell line wherein the cell line exhibits substantially no hybridization to a MoMLV retrovirus probe (the examiner can find no evidence in the art that CHO or BHK cells, for example, have endogenous MoMLV viruses) under stringent conditions, the cell line is α-galactosyl positive (i.e. Rother et al. suggests removal of some or most of the α-galactosyl

epitopes from the cell surface but nevertheless the cells themselves are inherently α-galactosyl positive), and said cell expresses a cellular targeting protein (i.e. env) and retroviral gag and pol genes in amounts sufficient to package said resistant retroviral particles and wherein a retroviral vector comprising a heterologous gene of choice is introduced into said packaging cells and is packaged into a retroviral particle. Rother et al. also recites a method for transferring heterologous genes into human or primate cells (i.e. brain cells) wherein the human serum resistant retroviral vector producing cells are contacted with the target cells *in vivo* (i.e. in the brain) and the heterologous gene is transferred (See Rother et al., Columns 21-22). With regard to the titers of retrovirus vectors produced (about 10^4 to about 10^8 pfu/ml), these titers are within the normal titers produced from standard retroviral producer cells known in the art and would be expected (absent evidence to the contrary) from those recited by Rother et al.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 2, 7, 12, 41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled

in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

A deposit of the Mpf cell line (ATCC Accession Number 1656-CRL) is required since this deposited material is claimed by it's specific ATCC address, i.e. in order to practice the claimed invention the skilled artisan would need unrestricted access to the specific material deposited at ATCC accession number 1656-CRL. Applicants are also reminded that the specification must be amended to specify the deposited material, the date of deposit, the correct address of the depository, etc. and if the deposit is made after the filing date of the application, section 37 CFR 1.804(b) must be complied with (See Attachment on Deposits of Biological Materials).

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-21, 36-38 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (and dependent claims) are vague in the recitation of the phrase "...exhibits substantially no hybridization to a Moloney-MLV retrovirus probe under stringent hybridization

conditions…". First, the term "substantially no hybridization" is unclear since "substantially" is a relative term with no frame of reference for comparison, i.e. substantially compared to what standard? Second, it is unclear what type of "probe" is being referred to, i.e. a retrovirus probe could be 10 nucleotides in length or the size of the entire MoMLV genome and the hybridization one would expect would vary depending on the size of the probe. Therefore, it is unclear what cells would be included within the claim language and therefore the metes and bounds of the claimed subject matter are unclear. Third, the claim is unclear since "stringent hybridization conditions" have not been identified in the specification and these conditions would be expected to vary depending on the definition of "stringent".

Claims 1, 6 and 11 (and dependent claims) are vague in the recitation of the phrase "capable of producing" or "capable of being packaged" or "capable of expression" since the capacity of a compound or composition to perform some function is merely a recitation of a latent characteristic of said compound or composition and said language carries no patentable weight.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached on (703) 308-4003. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo
September 7, 1999

DAVID GUZO
PRIMARY EXAMINER

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ATTACHMENT

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant or assignee, or a statement by applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection or rejection based on a lack of availability of biological material. Such a declaration:

1. Identifies declarant.

2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready availability thereto by the public if a patent is granted. The depository is to be identified by name and address (See 37 CFR 1.803).

3. States that the deposited material has been accorded a specific (recited) accession number.

4. States that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of the patent (See 37 CFR 1.808(a)(2)).

5. States that the material has been deposited under conditions that assure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 USC 122 (See 37 CFR 1.808(a)(1)).

6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit or for the enforceable life of the patent, whichever period is longer. See 37 CFR 1.806.

7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United

States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (e.g., see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, name and address of the depository, date of deposit and the complete taxonomic description.